K121366

SEP 7 2012

Infopia Co.,Ltd. Glycosylated Hemoglobin (HbA1c) Monitoring System
Special 510(k) for In Vitro Diagnostic Device

IV. 510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April/24/2012

1. Submission Sponsor

	Submitter
Name Address	Infopia Co.,Ltd. 891 Hogye-dong, Dongan-Gu, Anyang, Kyunggi, 431-080, Korea
Phone Fax Company contact	Phone: +82-31-460-0300 Fax: +82-31-460-0401 YJ Park

2. Submission Correspondent
   Official Correspondent for Infopia Co., Ltd.
   Maria Griffin
   mdi Consultants, Inc. 55 Northern Blvd., Suite 200
   Great Neck, NY 11021
   TEL: (516) 482-9001

3. Device

- Trade Name: Hemocue® HbA1c 501™ Glycosylated Hemoglobin test system
- Classification Name: Glycosylated Hemoglobin test system
- Classification regulation: 21 CFR 864.7470
- Product Code: LCP

4. Predicate Device:

CLOVER A1c ™ Glycosylated Hemoglobin Monitoring System (K082275) Infopia Co., Ltd.

5. Description:

The Hemocue® HbA1c 501™ Glycosylated Hemoglobin test system measures Hemoglobin A1c in venous and capillary whole blood. The Hemocue® HbA1c 501™ Glycosylated Hemoglobin test system includes Analyzer, Test cartridge, Check cartridges(Monthly and Daily), Thermal printer, Barcode scanner, PC cable and fan filter. The Hemocue® HbA1c 501™ Glycosylated Hemoglobin test system is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c(HbA1c, %) in human whole blood.

The Test Cartridge consists of a cartridge and a reagent pack containing the reagents necessary for the determination of hemoglobin A1c, with a sampling area for blood collection.

The reagent pack is pre-filled with reagent solution and rinsing solution. The reagent solution contains agents that hemolyse erythrocytes and bind hemoglobin specifically as well as a boronate resin that binds to the cis-diols of glycated hemoglobin.

The blood sample (4uL) is collected at the sampling area of the reagent pack, which is then inserted into the cartridge, where the blood is instantly lysed releasing the hemoglobin and the boronate resin binding the glycated hemoglobin.

The reagent pack containing the blood sample is inserted in Hemocue® HbA1c 501Analyzer (in which the cartridge has been placed). The cartridge is automatically rotated, placing the blood sample in the measuring zone. The total hemoglobin is photometrically measured by the diffused reflectance of the optical sensor composed of both a LED (Light Emitting Diode) and a PD (Photo Diode). The assembled cartridge is rotated and the rinsing solution washes out non-glycated hemoglobin from the blood sample, enabling photomectical measurement of glycated hemoglobin.

6. Indications for use:

The HemoCue® HbA1c501 assay is an in vitro diagnostic test that quantitatively measures the percent concentration glycosylated hemoglobin in capillary or venous whole blood samples for clinical laboratory and point of care use. Measurement of percent HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus. HemoCue® Hba1c501 is for in vitro diagnostic use and is not to be used for the diagnosis or screening of diabetes or for neonatal use.

The test is for prescription use as an aid in the management of diabetes.

7. Comparison to the Cleared Device

The device appearance (Analyzer &Test cartridge) has been changed, and glucose module function has been removed. Display resolution &Graphic User Interface design has been improved. Other than these modifications, the modified meter has the following similarities to the cleared device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same materials,
- adopts the same use environment and calibration method, and has the same shelf life.

8. Performance Data

Clinical: The clinical performance evaluation using the HemoCue® HbA1c501components were conducted for purpose of validating the professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the HemoCue® HbA1c501System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

9. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the HemoCue® HbA1c501System is as safe, as effective and performs as well as the legally marketed predicate device, CLOVER A1c ™ System (K082275).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Infopia Co., Ltd.
c/o Ms. Maria Griffin
MDI consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

SEP 7 2012

Re: k121366
Trade/Device Name: Hemocue HbA1c 501 Glycosylated Hemoglobin Monitoring System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: August 7, 2012
Received: August 9, 2012

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Hemocue® Hba1c 501 Glycosylated Hemoglobin Monitoring System

Indication For Use:

The Hemocue® Hba1c 501 assay is an in vitro diagnostic test that quantitatively measures the percent concentration glycosylated hemoglobin in capillary or venous whole blood samples for clinical laboratory and point of care use. Measurement of percent HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus. Hemocue® Hba1c 501 is for in vitro diagnostic use and is not to be used for the diagnosis or screening of diabetes or for neonatal use.

The test is for prescription use as an aid in the management of diabetes.

Prescription Use __√__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K121366